NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Single-incision short sling (mesh) insertion for stress urinary incontinence in women

Stress urinary incontinence is when urine leaks out during exercise or certain movements such as coughing, sneezing and laughing. It usually happens because the muscles and tissue that make up the pelvic floor have become weakened or damaged, most commonly associated with pregnancy. Single-incision short sling (mesh) insertion involves placing a short synthetic sling under the urethra (the tube that carries urine from the bladder) through an incision in the vagina. The aim of the sling is to support the urethra to reduce the chance of urine leaking when the bladder is put under pressure.

The National Institute for Health and Care Excellence (NICE) is examining single-incision short sling (mesh) insertion for stress urinary incontinence in women and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about single-incision short sling (mesh) insertion for stress urinary incontinence in women.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.

- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 20 June 2016

Target date for publication of guidance: September 2016

1. Draft recommendations

1.1. The evidence on the safety of single-incision short sling (mesh) insertion for stress urinary incontinence in women shows infrequent but serious complications including failure of the procedure, and persisting pain and discomfort. The evidence on efficacy in the long term is inadequate in quality and quantity. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research.

1.2. Clinicians wishing to do single-incision short sling insertion for stress urinary incontinence in women should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy, including that there is the potential for the procedure to fail and for serious long-term complications from the device, and provide them with clear written information. In addition, the use of NICE's information for the public *[[URL to be added at publication]]* is recommended.
- Enter details of all women having single-incision short sling insertion for stress urinary incontinence into a national register (at the British Society of Urogynaecology or the Female and Reconstructive Urology Section of the British Association of Urological Surgeons).

1.3 Patient selection should be done by a multidisciplinary team with experience in the assessment and management of women with stress urinary incontinence.

1.4 NICE encourages further research into single-incision short sling (mesh) insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection and long-term outcomes.

2. Indications and current treatments

2.1. Stress urinary incontinence is the involuntary leakage of urine during exercise or certain movements such as coughing, sneezing and laughing. In women, it is most commonly associated with previous pregnancy, with or without recognised obstetric trauma. Previous urogynaecological surgery may also result in stress urinary incontinence.

2.2. Conventional treatment is conservative, and includes lifestyle changes such as weight loss and pelvic floor muscle training. If the

condition does not improve, different types of surgery may be used, including intramural bulking procedures, insertion of a synthetic tension-free vaginal tape, insertion of a transobturator tape or other sling procedures, colposuspension or insertion of an artificial urinary sphincter.

3. The procedure

3.1. Single-incision short sling (mesh) insertion aims to reduce the risk of urinary leakage in women with stress urinary incontinence. The procedure also aims to minimise the risk of major adverse events such as bladder, vaginal, urethral and vascular perforations or erosions, and chronic pain that are associated with minimally-invasive sling procedures. The single-incision short slings have shorter tape lengths and different fixation systems to minimally-invasive slings. These fixation systems do not enter the obturator fossa (potentially minimising the risk of groin pain) or the retropubic space (minimising the risk of major vessel or visceral injury).

3.2. With the patient under local (with or without sedation), spinal or general anaesthesia, a small incision is made in the vaginal wall, under the urethra. The sling, which is typically 8–14 cm long, is inserted using a delivery needle through the obturator foramen and retracted to deploy the sling into the obturator internus muscle. This is repeated with a second sling on the contralateral side. A special tip anchors the sling in place behind the mid urethra. Sling tension is then controlled using the delivery device until the appropriate tension is achieved. The delivery device is then removed and the incision is closed. The slings are permanent implants. Cystoscopy is used to check that bladder perforation has not occurred during the procedure.

3.3. Single-incision short sling systems may differ in the length of the sling, the fixation method, the fixation location and the method of tension adjustment or control.

4. Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1. In a systematic review and meta-analysis of 3,308 women from 26 randomised controlled trials (RCTs) comparing single-incision mini sling (SIMS, n=1,735) procedures with standard midurethral sling (SMUS, n=1573) procedures in women with stress urinary incontinence, there was no significant difference in objective cure rates at a mean follow-up of 18.6 months between SIMS (tension-free vaginal tape [TVT] 'Secur' trials excluded) and SMUS (risk ratio [RR] 0.98; 95% confidence interval [CI], 0.94 to 1.01, n=11, I^2=7%). There were similar results when SIMS was compared with transobturator tension-free vaginal tape (TOT, RR 0.98; 95% CI, 0.94 to 1.01, n=10, I^2=11%) and with retropubic tension-free vaginal tape (r-TVT, RR 0.81; 95% CI, 0.48 to 1.40, n=1).

4.2. In the systematic review and meta-analysis of 3,308 women, there was no significant difference in patient-reported cure rates at a mean follow-up of 18.6 months between SIMS ('TVTSecur' trials excluded) and SMUS (RR 0.94; 95% CI, 0.88 to 1.00, n=11, I^2=57%). There were similar results when SIMS was compared with TOT (RR 0.96; 95% CI, 0.92 to 1.00, n=9, I^2=20%) and with r-TVT (RR 0.71; 95% CI, 0.42 to 1.20, n=2, I^2=75%).

4.3. In a Cochrane systematic review and meta-analysis of 3,290 women with stress urinary incontinence from 31 randomised or quasi-randomised trials, women were more likely to remain incontinent after surgery with SIMS (41% [121/292]) than with r-TVT (26% [72/281]; RR 2.08, 95% CI 1.04 to 4.14. Four out of 5 studies in the comparison included 'TVTSecur', which has been withdrawn from use as a single-incision sling. In the same study, incontinence rates were also higher with SIMS than with inside-out TOT (30% versus 11%; RR 2.55, 95% CI 1.93 to 3.36). However, if the trials in which 'TVTSecur' was not used were excluded, it showed that a high risk of incontinence was mainly associated with use of this device (RR 2.65, 95% CI 1.98 to 3.54). The evidence was insufficient to show a difference in incontinence rates with other SIMS ('TVTSecur' trials excluded) compared with inside-out or outside-in TOT.

4.4. In an RCT of 80 women (40 SIMS versus 40 TOT), there were no significant differences between groups for the cough stress pad test (CSPT) values before and after the procedure. However, there were significant differences within groups in CSPT values before and after the procedure (mean±standard deviation, grams: 71±18 versus 0.66±0.8 in the SIMS group, p=0.0001, and 73±27 versus 0.41±0.4 in the TOT group, p=0.0002).

4.5. In a prospective case series of 120 women treated by SIMS, the mean daily pad use decreased significantly from 2.4 before the procedure to 0.1 at 1 month and 0.2 at 12 months (p<0.01 versus baseline).

4.6. In a prospective comparative study of 240 women treated by SIMS (n=120) or r-TVT (n=120), detrusor instability scores did not change significantly in the SIMS group from baseline (2.1±1.3 versus 2.2±1.3 at 24 months after the procedure). In the r-TVT

group, the scores significantly worsened from baseline (2.4±1.5 versus 2.9±1.9 at 24 months, p<0.05).

4.7. In the prospective case series of 120 women, the mean urogenital distress inventory scores (a 6-item questionnaire) decreased significantly from 65% before the procedure to 3% at 1 month and 13% at 12 months (p<0.01 versus baseline).

4.8. In the prospective case series of 120 women, the mean Incontinence impact scores (a 7-item short-form questionnaire) decreased significantly from 87% before the procedure to 3% at 1 month and 13% at 12 months (p<0.01 versus baseline).

4.9. In an RCT of 225 women treated by SIMS (n=112) or TOT (n=113), the proportion of women using antimuscarinics 12 months after the procedure was significantly lower in the SIMS group than in the TOT group (6% [5/87] versus 16% [15/95], p=0.034).

4.10. In the systematic review and meta-analysis of 3,308 women, women with SIMS ('TVTSecur' trials excluded) returned to normal activities significantly earlier (weighted means difference [WMD] 5.08 days; 95% CI, −9.59 to −0.56, n=2, I^2=63%) and to work significantly earlier (WMD −7.20 days; 95% CI, −12.43 to −1.98, n=2, I^2=38%).

4.11. In the systematic review and meta-analysis of 3,308 women, there was no significant difference in quality-of-life scores (measured with the Incontinence Impact Questionnaire–Short Form IIQ7 and King's Health Questionnaire 7) between SIMS ('TVTSecur' trials excluded) and SMUS (WMD 1.23; 95% CI, -2.76 to 5.21, n=3, I^2=56%). All 3 RCTs included in the analysis reported improvement in quality-of-life scores at follow-up compared with baseline, with no significant differences between SIMS and SMUS.

4.12. In the prospective comparative study of 240 women treated by SIMS (n=120) or r-TVT (n=120), patient satisfaction (assessed using a visual analogue scale [0 to 10, from low to high satisfaction]) was 7.5±2.6 in the SIMS group compared with 7.4±1.7 in the r-TVT group (level of significance not stated).

4.13. In the systematic review and meta-analysis of 3,308 women, there was no significant difference in Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ12) scores between SIMS ('TVTSecur' trials excluded) and SMUS at a mean 18-month follow-up (WMD 0.39; 95% CI, −0.89 to 1.67, n=2, I^2=17%).

4.14. The specialist advisers listed the following key efficacy outcomes: objective and subjective cure of stress urinary incontinence, reduction in stress urinary leakage and reduction in stress incontinence episodes for more than 1 year.

5. Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1. Pain after the procedure was significantly lower in the single-incision mini sling (SIMS) group (tension free vaginal tape [TVT] 'Secur' trials excluded) than in the standard midurethral sling (SMUS) group (weighted means difference [WMD] −3.13; 95% confidence interval [CI] −4.89 to −1.36, n=4, I^2=93%, p<0.0005), and groin pain was also significantly lower (risk ratio [RR] 0.30; 95% CI, 0.18 to 0.49, n=10, I^2=19%, p<0.00001) in a systematic review and meta-analysis of 3,308 women from 26 randomised controlled trials (RCTs) comparing SIMS procedures (n=1,735) with

SMUS (n=1,573) procedures in women with stress urinary incontinence.

5.2. Haemorrhage during the procedure was reported in 2% (2/120) of women in the SIMS group (including treatment with 'TVTSecur' slings) and in 1% (1/120) of women in the retropubic TVT (r-TVT) group in a prospective comparative study of 240 women. In the same study, haemoglobin drop within 30 days of the procedure was reported in 1% (1/120) of women in the SIMS group and in none of the women in the r-TVT group (p value not significant). Pelvic haematoma was reported in 1 woman in a prospective case series of 116 women treated by SIMS; it developed after revision surgery needed because of urinary outlet obstruction.

5.3. Vaginal tape erosion rates were not significantly different between the SIMS group ('TVTSecur' trials excluded) and the SMUS group in the systematic review and meta-analysis of 3,308 women (RR 1.43; 95% CI, 0.61 to 3.35, n=11, I^2=0%, p=0.41). Vaginal mesh exposure rate was significantly greater in the SIMS group ('TVTSecur' trials included) than in the transobturator sling (TOT) group in a Cochrane systematic review and meta-analysis of 3,290 women with stress urinary incontinence from 31 randomised or quasi-randomised trials (RR 2.59, 95% CI 1.21 to 5.56, n=9, I^2=4%, p=0.015). In the same systematic review, bladder or urethral erosion rate was significantly greater in the SIMS group ('TVTSecur' trials included) than in the TOT group (RR 17.79, 95% CI 1.06 to 298.88, n=2, I^2=0%, p=0.046). Mesh extrusion was reported in 4% (4/113) of women in the prospective case series of 116 women with stress urinary incontinence treated with SIMS, within 12 months of the procedure. Three of the 4 mesh extrusions were treated by revision surgery that included trimming and

excision; 1 mesh extrusion was asymptomatic and successfully treated with oestrogen cream.

5.4. Urethrovaginal fistula was reported in 1 women treated by SIMS in a single case report. The same patient had also bladder mesh erosion and vaginal mesh exposure. She was treated by excision of midurethral mesh, urethroplasty, Martius flap tissue transfer and cystourethroscopy but continued to have mild stress urinary incontinence.

5.5. De novo urgency or worsening of pre-existing surgery rates were not significantly different between the SIMS group ('TVTSecur' trials excluded) and the SMUS group in the systematic review and meta-analysis of 3,308 women (RR 1.09; 95% CI, 0.78 to 1.54, n=12, I^2=0%, p=0.61).

5.6. Repeat continence surgery rates were not significantly different between the SIMS group ('TVTSecur' trials excluded) and the SMUS group in the systematic review and meta-analysis of 3,308 women (RR 2.00; 95% CI, 0.93 to 4.31, n=10, I^2=0%, p=0.08).

5.7. Lower urinary tract injury rates were not significantly different between the SIMS group ('TVTSecur' trials excluded) and the SMUS group in the systematic review and meta-analysis of 3,308 women (RR 0.99; 95% CI, 0.38 to 2.56, n=13, I^2=0%, p=0.99). Bladder perforation was reported in 3% (3/120) of women in a prospective case series of 120 women. The patients were treated with a Foley catheter overnight, which was removed 1 day after the procedure.

5.8. Vaginal wall perforation was reported in 1% of women in the SIMS group, in 3% of women in the TVT group and in 4% of women in

the TOT group in a retrospective comparative study of 531 women (relative number of women not reported).

5.9. Voiding difficulties after the procedure rates were not significantly different between the SIMS group ('TVTSecur' trials excluded) and the SMUS group in the systematic review and meta-analysis of 3,308 women (RR 0.58; 95% CI, 0.26 to 1.31, n=11, I^2=31%, p=0.19).

5.10. Urinary tract infection within 30 days of the procedure was reported in 3% (3/120) of women in the SIMS group and in 4% (5/120) of women in the r-TVT group in the prospective comparative study of 240 women (p value not significant).

5.11. A bladder stone was reported in 1 woman 3 years after the procedure in a second case report. It was treated by excision of mesh transvaginally, separation of the stone from the eroded mucosal mesh and subsequent transurethral stone removal. The patient continued to have persistent stress urinary incontinence that had worsened after SIMS removal. She was subsequently treated with periurethral bulking and her symptoms of stress urinary incontinence improved.

5.12. Dyspareunia was reported in 1 woman in the prospective case series of 116 women, within 12 months of the procedure.

5.13. Inflammation was reported 1 woman in the prospective case series of 116 women, within 12 months of the procedure.

5.14. Delayed wound healing was reported 1 woman in the prospective case series of 116 women, within 12 months of the procedure.

5.15. Anchor displacement was reported in 1 woman at the 1-year follow-up visit in the RCT of 80 women (40 SIMS versus 40 TOT).

The anchor was removed with the patient under local anaesthesia and the patient remained continent.

5.16. In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not list any new anecdotal adverse event. They considered that the following were theoretical adverse events: reaction to tape and poor anchoring of tape leading to failure in the short- or long-term.

6. Committee comments

6.1. The committee noted there are a number of different devices in use.

6.2. The committee was informed that removal of the device may be complex, may require multiple procedures and should only be done by people with expertise in this specialised surgery.

6.3. The committee noted that, despite the existence of 2 registries, data collection had been disappointing.

6.4. The committee encouraged the reporting of all device-related adverse events to the Medicines and Healthcare Products Regulatory Agency.

6.5. The committee was advised that a national standard consent form is being developed.

7. Further information

7.1. For related NICE guidance, see the NICE website.

7.2. This guidance is a review of NICE's interventional procedure guidance on single-incision sub-urethral short tape insertion for stress urinary incontinence in women.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

May, 2016